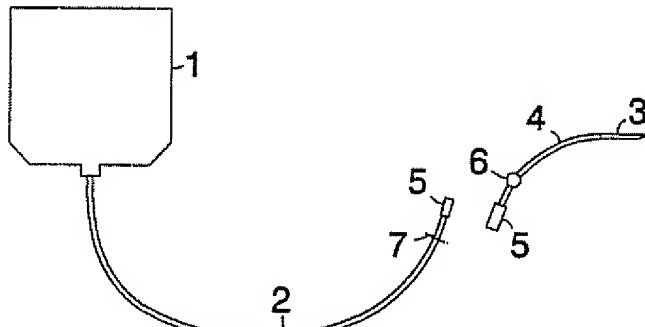


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: A METHOD RELATING TO COLLECTING BLOOD SAMPLES IN CONJUNCTION WITH BLOOD TAKING PROCESSUS		
		
(57) Abstract A method pertaining to sampling blood in conjunction with blood taking processes and manual plasmapheresis with the aid of a blood bag (1) and connecting hose (2, 4) and a needle (3) which is intended for insertion into the blood donor, in a known manner. The method is characterized in that the hose is provided with a hose coupling (5) and in that a hose clamp (6) is fitted between the coupling and the needle. When sampling blood, the hose (2, 4) is closed-off on both sides of the coupling (5) and the coupling is then loosened and that part of the coupling which is connected to the needle-accommodating part of the hose (4) is connected to a sub-pressure sleeve or the like, in which one or more sub-pressure tubes or the like in sequence is/are inserted for collecting blood samples.		

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A method relating to collecting blood samples in conjunction with blood taking processes

5 The present invention relates to a method according to the preamble of Claim 1.

Present day methods of collecting blood samples in conjunction with a blood taking process, and in conjunction with manual plasmapheresis, are unacceptable
10 from the aspect of infection and contagion.

A hose extends from the needle inserted into the blood donor to a blood bag and possible accessories. The bag is typically placed on scales which detect when the
15 correct amount of blood has been taken from the donor, whereupon the hose is automatically clamped tightly in the vicinity of the blood bag, thereby throttling the blood flow. A metal clip is then attached to the hose and the hose is severed between the metal clip and a
20 pair of hemostatic forceps, whereafter the blood bag is taken away for further treatment. The blood is emptied from the bag into open test tubes, by opening the forceps attached to that part of the hose which is connected to the needle. Subsequent to having filled one or
25 more test tubes with a given amount of blood, this amount being judged solely by looking at the test tubes, the open test tubes are carried to a bench. Loose stoppers are now inserted into respective tubes, which are then shaken on a rotating disc, in a conventional manner.
30

This hitherto applied method of procedure has many drawbacks. For instance, the hose is clipped-off with the aid of scissors (the same pair of scissors throughout the working day), which incurs the risk of blood
35 spillage and dirty scissors. Furthermore, the blood is

emptied into open tubes, which incurs the risk of further blood spillage and of blood being deposited on the outer surfaces of contaminated tubes. The blood can easily splash-up from the tubes as the results of involuntary knocks during transportation of the tubes and as the tubes are placed onto a bench. The application of loose stoppers or corks means that the stoppers may loosen from the tubes as they sit on the rotating disc. On the other hand, if the stoppers are pressed too hard in the tubes, there is a risk of the tubes breaking and resulting in further blood spillage and possible cuts to the person handling the tubes. The personnel handling the blood taking equipment are thus exposed to very serious risks of contagion and infection, with the serious consequences that this implies.

The object of the present invention is to fully eliminate the drawbacks of the aforescribed, earlier known method of procedure, and therewith also to eliminate the risk of infection to the personnel handling the blood taking equipment. These objects are achieved in accordance with the invention with the method defined in the characterizing clauses of the following claims.

The invention will now be described in more detail with reference to the accompanying drawing, which illustrates schematically a method of procedure when taking blood from a blood donor.

Figure 1 is a schematic illustration of a blood taking process and shows the initial stage of a blood sampling process; Figures 2 and 3 illustrate schematically a first stage of a blood sampling process; Figure 4 illustrates the second stage of a blood sampling process; and Figure 5 illustrates the third stage of a blood sampling process in larger scale.

Shown in the drawing is a blood bag 1 and a hose 2 extending from said bag. The needle to be inserted into the blood donor is referenced 3 and is connected to a hose part 4 which is connected to the hose 2 by means of a hose coupling 5 (in the illustrated case a known Luer cap fitting). The hose part 4 is also provided with a hose clamp 6.

Figure 1 illustrates the situation in which the needle 3 is attached to the donor, the hose clamp 6 is open and blood is drained into the bag 1.

When the bag has received the correct amount of blood, as indicated by means of the scales mentioned in the introduction, the hose 2 is squeezed together with the aid of some type of clamp which cannot be opened, for instance a metal clip, or the hose may be heat-fused together (as indicated schematically at 7 in Figures 2 and 3). The clamp 6 is activated to seal-off the hose part 4, whereafter the hose 2 is released from the hose part 4 through the agency of the hose coupling 5.

The blood bag 1 and hose 2 are removed for further processing.

The coupling 5 (Luer cap fitting) of the hose part 4 is then connected to a known sleeve for sub-pressure tube 9 - see Figure 4. Inserted in the sleeve in a known manner is a needle-like adapter 10 (see Figure 5) which is surrounded by a stocking 11 which can be penetrated by the needle. It shall be understood that the sleeve 9 has a hose coupling (Luer cap fitting) which fits onto the hose coupling 5.

A test tube under sub-pressure and fitted with a rubber stopper is inserted in the sleeve, so that the needle

10, which is displaced by the stocking 11, penetrates the stopper 13. The hose clamp 6 is opened and the tube 12 is filled with an exact amount of blood, as a result of the sub-pressure prevailing in the tube.

5

The sub-pressure tube 12 is then removed and the hole made by the needle 10 in the stopper closes automatically as the rubber in the stopper 13 reasserts itself.

10 The tube 12 can now be transported away for further processing of the blood, without risk of blood spilling therefrom.

15 It will be evident from the aforescribed method steps that no blood will be spilled or contaminate the person taking or sampling the blood, while each tube can be filled with an exact quantity of blood.

20 The problem can also conceivably be solved by attaching a so-called Y-coupling to an additional hose for blood sampling purposes. In this case, the additional hose must be provided with a fracture pin or a hose clamp and also a Luer cap stopper at one end. This method would enable samples of blood to be taken during the actual
25 blood letting process.

Subsequent to running tests on the basis of this concept, the idea was shelved because the blood remained stationary in the hose and the Y-piece activates coagulation factors which can be carried down into the collecting vessel, which most certainly must not happen.
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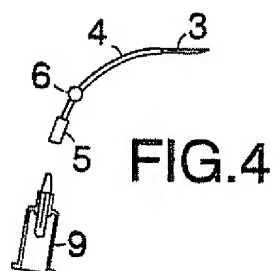
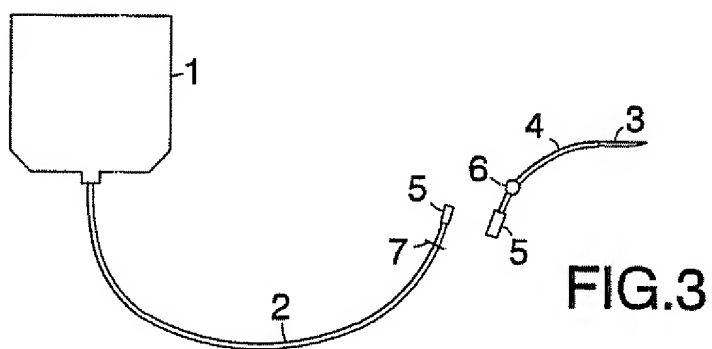
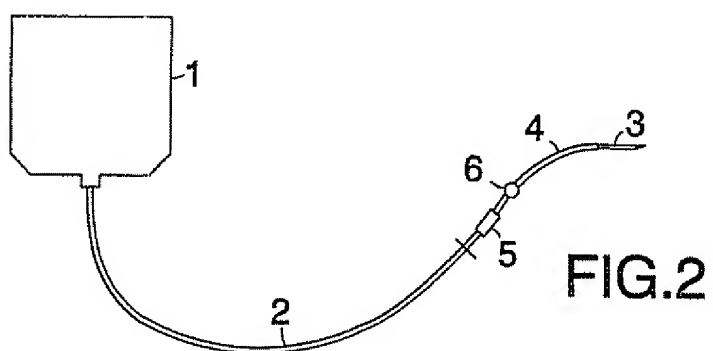
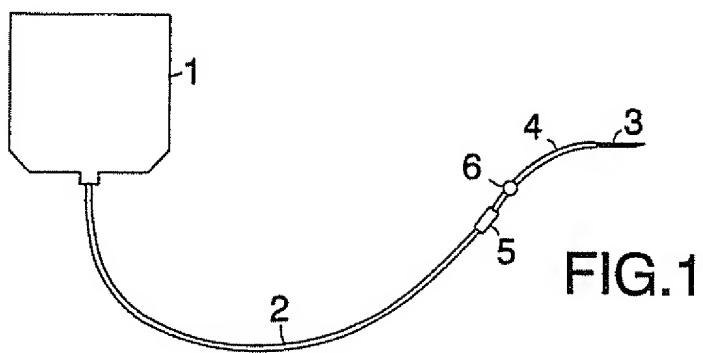
This risk is totally eliminated with the concept first described, since the blood collecting vessel is disconnected during the actual blood taking process. This
35 solution is also extremely easy to apply, cheap in

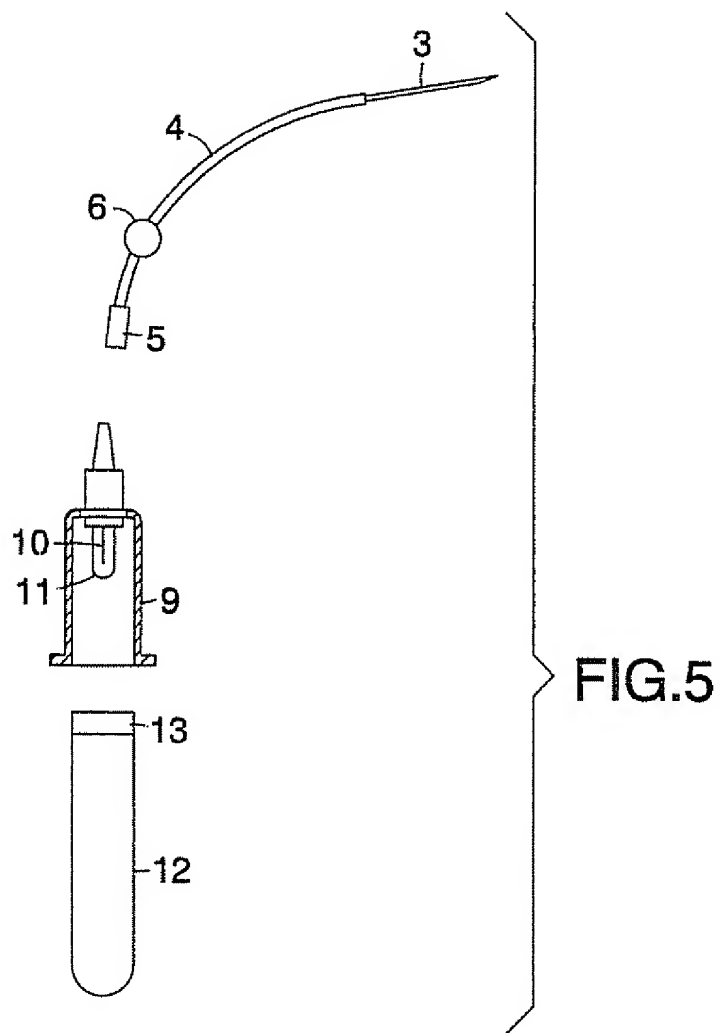
manufacture, readily sterilized and readily packaged.

In order to enhance the safety of the system, the coupling (the Luer cap fitting) may be provided in practice with some form of seal when fitted for delivery, for instance a shrink plastic covering, so that the receiver is able to ascertain whether or not the coupling is intact and therewith sterile.

CLAIMS

1. A method pertaining to taking blood samples in conjunction with blood taking processes and manual plasma-
5 pheresis with the aid of a blood bag (1) and a connecting hose (2, 4) provided with a needle (3) which is intended for insertion into the blood donor, in a known manner,
c h a r a c t e r i z e d by fitting the hose with a
10 hose coupling (5); fitting a hose clamp (6) between said coupling and said needle, such that the hose is closed-off on both sides of the coupling (5) when sampling blood; releasing the coupling; connecting that part of the coupling which is connected to the part of the hose
15 (4) provided with said needle to a sub-pressure sleeve (9) or the like in which a sub-pressure tube (12) or the like or a sequence of sub-pressure tubes (12) or the like is/are introduced for collecting a blood sample.
- 20 2. A method according to Claim 1, c h a r a c -
t e r i z e d by using a coupling in the form of a Luer cap fitting (5).
- 25 3. A method according to Claim 1 or 2, c h a r a c -
t e r i z e d by closing-off that part of the hose (2) which is connected to the bag (1) by heat-fusing said hose or with the aid of a hose clip.





INTERNATIONAL SEARCH REPORT

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PCT/SE 93/00463

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61B 5/14, A61M 1/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61B, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, A1, 8909025 (HANSBY, MARIA), 5 October 1989 (05.10.89), figure 1, abstract ---	1-3
A	EP, A2, 0356002 (CITY OF HOPE), 28 February 1990 (28.02.90), figures 2,4, abstract ---	1-3
A	US, A, 4676783 (JANINE C. JAGGER ET AL), 30 June 1987 (30.06.87), figures 2,3, abstract ---	1-3
A	WO, A1, 8706813 (ROBERTI, LAMBERTO), 19 November 1987 (19.11.87), see the whole document ---	1-3

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP, A1, 0002028 (WALTER SARSTEDT KUNSTSTOFF-SPRITZGUSSWERK), 30 May 1979 (30.05.79), see the whole document -----	1-3

INTERNATIONAL SEARCH REPORT
Information on patent family members

26/08/93

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